



April 3, 2015

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National Coordinator for Health Information Technology
Department of Health and Human Services

Submitted at <http://www.healthit.gov/interoperability>

Re: Connecting for Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap, Draft Version 1.0

Dear Dr. DeSalvo:

The College of Healthcare Information Management Executives (CHIME) and the Association of Medical Directors of Information Systems (AMDIS) welcome the opportunity to submit comments regarding the Nationwide Interoperability Roadmap, Draft Version 1.0.

CHIME has more than 1,400 members, composed of chief information officers (CIOs) and other top information technology executives at hospitals and clinics across the nation. CHIME members are responsible for the selection and implementation of clinical and business information technology (IT) systems that will facilitate healthcare transformation. AMDIS is the premier professional organization for physicians responsible for healthcare IT. With more than 2,800 physician members worldwide, 250 associate members and 40 provider organization members, AMDIS members are the thought leaders, decision makers and opinion influencers dedicated to advancing the field of Applied Medical Informatics and improving the practice of medicine through IT.

Both organizations share the vision of an e-enabled healthcare system as described by the many efforts under way at the Department of Health and Human Services.

Before offering thoughts specific to various sections of the Roadmap, we wish to highlight a handful of overarching principles and recommendations.

1. **Patient identification is paramount if we are to make any progress toward an interoperable Learning Health System (LHS).** Foundational to the vision espoused by the Roadmap is the ability of providers to accurately and consistently match patients with

their data. A national approach to patient identification is prerequisite for interoperability and the lack of a standard patient identifier only serves to aggravate our industry's technical challenges. Without a standard patient identifier, the creation of a longitudinal care record, composed of data created through disparate systems, geographies and chronology is simply not feasible. Future drafts of this roadmap must enable development of a standard patient identifier.

2. **CHIME and AMDIS are supportive of the process established by this Roadmap to prioritize standards across several important domains.** We also support the concept of a common clinical data set that adheres to clear, enforceable national standards.
3. **We caution against being overly ambitious with the development of a nationwide governance mechanism and encourage focused prioritization through ingrained collaboration among private and public sector stakeholders.** In our view, interoperability in the service of high quality, safe patient care should remain the principal focus of the near-term.
4. **CHIME and AMDIS support the need for additional testing tools, including scenario-based testing and exception handling, and we agree that their development and use are critical actions for stakeholder assurance that HIT is interoperable.** We also underscore the need to have a post-certification surveillance program steeped in assuring conformance to requirements established by certification.
5. **CHIME and AMDIS also encourage policymakers to think more critically about how to recognize the vital role that patients and their family play as a point of integration of disparate health information.** Patients can be powerful mediators of their own medical records and care plans towards the synchronization of services delivered across different settings of care. We believe it is an operational necessity for policymakers to enable patients to be conduits of information towards better, safer care delivery.

One issue that was absent the Roadmap, but should garner equal attention is that of electronic clinical quality measurement. Beyond clinical data exchange and interoperability, HHS has misaligned policies around clinical quality measurement. As the future of pay-for-value reimbursement is contingent on the ability to attribute performance, the Centers for Medicare and Medicaid Services (CMS) and ONC should prioritize a unified strategy for capturing and communicating quality in healthcare. Below are three recommendations related to quality measurement that should be considered alongside interoperability policy improvements.

1. Implement aggressive and thorough comprehensive quality measures testing within the CMS and ONC to ensure measures are adequately defined and tested before requiring them for use in federal reporting programs.
2. Ensure that all quality reporting requirements are coordinated and consistent within federal reporting/incentive programs within 18 months.
3. Establish and adequately fund a National Measurement Enterprise consisting of open and transparent measure development, measure endorsement (e.g. National Quality Forum), and measure application (e.g. NQF's Measure Applications Partnership).

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Rules of Engagement and Governance

The draft Roadmap includes a call to action, for “[p]ublic and private sector stakeholders across the ecosystem to come together to establish a single coordinated governance process to establish more detailed policies regarding business practices, including policies for identifying and addressing bad actors and to identify the technical standards that will enable interoperability for specific use cases,” with ONC defining “a nationwide governance framework with common rules of the road.” While we agree with the direction signaled by the roadmap, there are many ways in which the goals of the governance mechanism could be achieved.

Nonetheless, CHIME and AMDIS believe that advancing the interoperability cause requires standardization in certain areas, most notably with respect to patient identification, consent policy, and the exchange of a specified data set. In this regard, it would be important for stakeholders to come together to reach consensus on the topics in need of immediate attention, while avoiding the temptation to do everything at once. We believe such prioritization will be critical and should be developed collaboratively among private sector stakeholders and the federal government without an overly prescriptive, top-down process. Instead, ONC and other federal agencies should be active partners with industry in governance across the various domains, such as standards development, rules of the road, and testing.

In addition, for key areas, it is not simply a question of having standards, but of having standards that are relatively specified and are not open to multiple interpretations and uncontrolled variations, and that meet provider and other stakeholder needs. Further, while consideration needs to be given to mechanisms for enforcing standards, we believe it would be a mistake to underappreciate the power of the marketplace. More specifically, if each individual chief information officer’s health information technology purchasing decisions were guided by whether a product did or did not meet essential standards related to interoperability, we predict that the marketplace would quickly respond to these signals.

The draft Roadmap also expresses the goals of specifying policies that address needs beyond treatment, including but not limited to payment and health care operations and patient-generated health data. The document also envisions the development of future policies for interoperability of health information from non-clinical sources and of clinical data to support research and big data analyses. CHIME and AMDIS believe that the Roadmap correctly identifies the order in which issues should be tackled. However, we caution against attempting to do too much too quickly. In our view, interoperability in the service of high quality, safe patient care should remain the principal focus of the near-term.

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Certification and Testing to Support Adoption and Optimization of Health IT Products and Services

We support the need for additional testing tools, and agree that their development and use are critical actions for stakeholder assurance that HIT is interoperable.

With respect to certification programs, CHIME and AMDIS agree about the importance of developing standards applicable to long-term and post-acute care, home and community based services in non-institutional settings and behavioral health settings. These settings are obviously relevant to both transitions of care and care coordination. We would note, however, that providers in these settings have largely been ignored by state and Federal electronic health record (EHR) incentive programs, and thus any mandate to adopt HIT technology meeting certain standards would be an unfunded mandate for them. Further, we believe that these other settings will have unique needs and thus would benefit from special standards. As a result, consideration needs to be given to sub-certifications rather than expecting that every HIT product will be certified “for everything.”

CHIME and AMDIS would also note that the goal of interoperability needs to account not only for exchanges between organizations (which is understandably the prime focus now), but must also take into account the many ways in which data and other information could conceivably be transmitted to, and incorporated in, an EHR (e.g., through a wide range of devices). We also believe that it will be important to ensure that all stakeholders define interoperability in the same way. Our concern is that the term appears to be given a wide range of meanings by product vendors and others. What one stakeholder might label interoperable might not efficiently and effectively meet the interoperability needs of other stakeholders.

We also agree that more stringent testing will be important in the certification context, including the use of scenario-based testing and post-implementation testing. For example, it is not sufficient to know whether an HIT product has certain basic capabilities, it is also important to know how that product reacts to common scenarios (such as the failure to populate all required fields). We would note, however, that in our experience, the basic problem has not been with testing or certification, but stems from standards that are too open or loose, or that can be too easily misapplied (e.g., when fields are misused). Thus, focusing only on testing and certification misses the point that the standards are what is being tested and certified against. Thus, problems with the standards themselves (e.g., where they are inadequate to meet provider needs, including the need for true interoperability) will not be addressed by more vigorous testing or more rigorous certification procedures. Rather, these issues will need a more comprehensive solution that looks at standards development, implementation and post-certification surveillance. We also encourage more emphasis on usability of products as part of this entire process.

Finally, CHIME and AMDIS believe that the certification process needs to do a better job of ensuring that users of certified technology can successfully pass an audit (e.g., an audit of whether they have satisfied meaningful use requirements while using the certified technology). We recognize that this will require greater coordination between those who commission such audits, the standards

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development organizations, HIT certification bodies, and product vendors. Nonetheless, we consider this a high priority issue.

Core Technical Standards and Functions

Consistent Data Formats and Semantics

CHIME and AMDIS agree that annual publication of a list of best available standards and implementation guides would be helpful but its value will depend heavily on the availability of mechanisms to require or strongly encourage their incorporation by vendors as well as their proper use. We would add that the generation of such a list should be guided by the desire to meet provider needs. In addition, any standards and implementation guides need to be as specific as possible to avoid multiple interpretations or variations that serve to impede interoperability. Further, we are concerned that existing standards are often misused (e.g., fields intended for one purpose are hijacked for another, or many others), without any obvious ramifications for the offenders. In short, an annual list of best available standards will be helpful but only if those standards meet provider needs and facilitate interoperability, and only if they are actually used.

CHIME and AMDIS also agree that greater standardization, especially with respect to the common clinical data set, would be of tremendous value in facilitating interoperability. For example, for the data element sex (gender), we believe that stakeholders would benefit from greater standardization of nomenclature. But, again, a key determinant of the value of such standardization will be the available “enforcement” mechanisms, whether they involve governmental action, public-private enforcement mechanisms, or simply the demands of the marketplace.

We note, too, that the draft Roadmap (on page 85) envisions that states and other stakeholders across the ecosystem would further explore and determine the role that the National Information Exchange Model can serve with regards to supporting health care and human services interoperability. We wish to use this reference as a springboard for emphasizing the importance of involving states in all aspects of the interoperability topic; states are key players and they can have a significant impact on other stakeholders, including health care systems located in multiple states. Thus, their active involvement is essential.

In this regard, we would also express some reservations regarding the expectation that guidance alone will produce the results needed to facilitate interoperability. Instead, we believe that there needs to be a sufficient degree of “enforced” standardization, rather than expecting non-binding guidance to advance interoperability. Of course, in saying this, we also recognize that there is a risk of inhibiting innovation if standardization is carried too far, and thus a reasonable balance needs to be struck. In this regard, we believe that standardization with respect to the common clinical data set and enforcing the correct use of data fields would be the appropriate places to focus near-term attention.

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Accurate Individual Data Matching

Pages 94 and 95 of the draft Roadmap list critical actions for accurate individual data matching. The Roadmap also provides a fair amount of related background information. CHIME and AMDIS appreciate the fact that ONC is devoting considerable attention to this very important topic. However, we were greatly disappointed at the failure to even mention one approach that we believe is much more promising than the alternatives described in the Roadmap—a unique health identifier. We suspect the omission might, in part, be due to the unfortunately longstanding Congressional prohibition against the use of appropriated dollars to promulgate or adopt any final standard providing for the assignment of a unique health identifier until legislation is enacted specifically approving the standard.

In any case, we have little or no confidence that other approaches, such as deterministic or probabilistic matching, will be sufficiently robust to meet the needs, and we believe that errors affecting individual data matching will have unfortunate patient safety consequences. We do not believe that other industries would tolerate the error rates seen under the various matching algorithms available for use in the healthcare sector and we do not believe that patients would be happy to know that their welfare is dependent, in part, on such algorithms. In addition, we are concerned that inadequacies in data matching protocols end up imposing unnecessary liability on healthcare providers. In short, CHIME and AMDIS believe that highly accurate individual data matching is foundational to interoperability success and to an effective and efficient health care system, and we urge all stakeholders, including the U.S. Congress, to revisit the issue of unique health identifiers. For that reason, we are not submitting comments regarding the alternative actions described in the draft Roadmap.

Priority Use Cases

Appendix H of the draft Interoperability Roadmap listed 56 priority use cases submitted to ONC through public comment, listening sessions, and federal agency discussions. CHIME and AMDIS were happy to contribute to this process. The draft Interoperability Roadmap specifically asks stakeholders to identify 3 priority use cases from the list in Appendix H that should inform priorities for the development of technical standards, policies and implementation specifications.

Selecting only 3 use cases for submission was not an easy process. First, as we emphasize above, patient identity proofing is a cornerstone task that deserves every possible attention. If this issue is not successfully addressed, it essentially makes any prioritization of use cases a rather meaningless exercise. Second, as we examined and discussed the 56 use cases listed in Appendix H, we concluded that many of them were closely related and that some were quite broad and arguably encompassed other use cases on the list. All of this made it difficult to identify 3 use cases warranting greater attention than others. In fact, if restricted to 3 use cases, CHIME and AMDIS members were inclined to favor the broader use cases, such as Use Case 33, Providers have the ability to query data from other sources in support of care coordination (patient generated, other providers, etc.) regardless of geography or what network it resides in, which CIOs felt could easily

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encompass other use cases listed in Appendix H. However, we were concerned that such broad use cases might be less helpful in prioritizing the development of technical standards, policies and implementation specifications.

The above comments notwithstanding, we believe that the following 3 use cases are high priority:

- Use Case 6, Providers and their support staff should be able to track all orders, including those leaving their own organization and EHR, to completion;
- Use Case 18, Patients have the ability to access their holistic longitudinal health record when and where needed; and
- Use Case 20, Patients, families and caregivers are able to use their personal devices such as smartphones, home BP cuffs, glucometers and scales to routinely contribute data to their longitudinal health records and use it or make it available to providers to support decision-making.

Our rationale for flagging these 3 uses cases for special attention is given below.

Use Case 6 acknowledges that hospitals, their medical staff, and others have made significant investments in computerized order entry and that this work should be built upon to allow for orders to be followed to completion. This would serve as a provider workload enhancer and have positive implications for patients, including more timely notification of their test results, as well as ensuring that ordered tests are done and the results efficiently assessed and incorporated into patient medical records. And this use case is obviously of special importance when an order must go outside of the four walls of a given provider or outside of an organized delivery system.

Use Case 18 speaks to the need to have a central place for patients to access all of their medical information, most likely as part of a personal health record, which is efficiently populated by data from various providers. Of course, this is likely to require consumers to become more participatory in their care. In other words, interoperable information technology can certainly help but would not be a complete solution by itself.

Use Case 20 addresses the need to efficiently incorporate patient- and caregiver-generated information into patient health records in a way that facilitates its use by both patients and their providers. We would expect this to enhance decision-making and improve patient care.

CHIME and AMDIS support the important reform initiatives at the CMS Innovation Center and we support CMS's vision for a 21st century Medicare delivery system. As part of that system, healthcare CIOs and CMIOs are ready to implement the technology and processes that will enable the tenets of better care for individuals; better health for populations; and lower growth in expenditures to become a reality. If there are any questions about our comments or more information is needed, please contact Leslie Krigstein, Interim Vice President of Public Policy, CHIME, at lkrigstein@chimecentral.org or (202) 507-6158. We look forward to a continuing dialogue with your office on this and other important matters.

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Sincerely,



Russell P. Branzell, CHCIO, LCHIME
President and CEO
CHIME



William F. Bria MD
Chairman of the Advisory Board
AMDIS